



UNDP-GEF Enabling Activities Project

**Government of Malaysia
United Nations Development Programme**

Support to Capacity Building Activities on Implementing the Cartagena Protocol on Biosafety

(MAL/03/G31-PIMS 2182)

**Inception Report
2007**

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EXECUTIVE SUMMARY

Though the Project Brief for this ***Support to Capacity Building Activities on Implementing the Cartagena Protocol on Biosafety*** in Malaysia was approved in 2002, the preparation and finalization of this Project Document was delayed because the tabling of the Biosafety Bill to the Malaysian Cabinet was delayed as the inter-ministerial consultation on the Bill took more time than expected. Moreover, in 2004 a cabinet reshuffle saw some delay in finalizing the Project Document as the former Ministry of Science, Technology and the Environment was split into two separate ministries i.e. Ministry of Science, Technology and Innovations and Ministry of Natural Resources and Environment. The project was finally approved by UNDP-GEF in 2006 allocating a total of USD 911, 380 for three years.

The project is led by the Conservation and Environmental Management Division (CEMD) under the Ministry of Natural Resource and Environment (NRE) with support from UNDP Malaysia. The objective of this project is to help consolidate Malaysia's national capacity for the implementation of the Cartagena Protocol on Biosafety as well as the National Biosafety Act of 2007. The project will address the capacity building needs of Malaysia to enable the country to implement her National Biosafety Act Specifically, the project will develop national capacities in biosafety required to carry out risk assessments with appropriate scientific and technical skills; implement necessary activities for risk management; evaluate and strengthen the legal and regulatory frameworks and develop infrastructure for information exchange and data management, as well as achieve broad social participation in biosafety matters. The development of national capacities in these areas will consolidate the national framework for biosafety management, with lasting impact on Malaysia's vision to utilize biotechnology for sustainable development and economic growth.

During the inception phase, the Principal Assistant Secretary of CEMD was appointed as the National Project Director (NPD). An Inception Workshop was held on 19th of July 2007 at Equatorial Bangi, Putra Jaya with the objective of informing all stakeholders the overall objectives of the project and also give them an opportunity to comment critically and give suggestions to the smooth and effective implementation of the project A total of 97 participants from various sectors including government agencies, academia and research institutions, NGOs and private sector attended the workshop. A summary of the

inception workshop report is appended as **Annex 9**. In the inception workshop, the participants were divided into 6 groups based on their affiliations. The Strategic Results Framework (**Annex 1**) was amended to include most of the comments and suggestions where relevant from these groups.

A National Steering Committee will be formed to assess and monitor the project's work plan and its results framework. This first meeting scheduled for September 2007 will then review and endorse the inception report, the strategic results framework and the budget.

In the process of implementing this project, several challenges have been identified. The huge task ahead of this project to support capacity building activities to implement the Biosafety law will have to attempt to rectify and overcome some of these challenges, and move ahead with planning of a set of activities/workshops that is more cohesive in nature, emphasizing the importance of continuity of both the human resource factor as well the sustainability of various stakeholders. The project team will endeavor to do its best to make this project a success which can be measured in terms of ability of the National Biosafety Law fully enforced and operational.

The project would like to take this opportunity to thank the CEMD officials, UNDP Malaysia and all stakeholders both government and NGOs for their valuable contribution in the preparation of this report.

LIST OF ABBREVIATIONS

AIA	Advanced Informed Agreement
BCH	Biosafety Clearing-House
CBD	Convention on Biological Diversity
CEMD	Conservation and Environmental Management Division
COP	Convention of Parties
CPB	Cartagena Protocol on Biosafety
GEF	Global Environment Facility
GMAC	Genetic Modification Advisory Committee
GMF	Genetically Modified Food
GMO	Genetically Modified Organism
GoM	Government of Malaysia
IBC	Institutional Biosafety Committee
IPR	Intellectual Property Right
ISS	Implementation Support Service
LMO	Living Modified Organism
MTA	Material Transfer Agreement
NBB	National Biosafety Board
NBBnet	National Biotechnology Network
NGO	Non Governmental Organisation
NPBD	National Policy on Biological Diversity
NPC	National Project Coordinator
NRE	Ministry of Natural Resources and Environment
NSC	National Steering Committee
PMU	Project Management Unit
TOR	Terms of Reference
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme

INTRODUCTION

This document is a concise report of the UNDP/GEF support to capacity building activities on implementing the Cartagena Protocol on Biosafety (CPB) at the time of completion of the Project Inception Phase and start of full project implementation. It presents the UNDP Project Document, with the main outputs expected at the end of the project, the inception workshop report and the amended project activities after taking into consideration the inputs from the various stakeholders.

The document presents the key project planning and implementation tools, the most important of which are as follows:

- Project Inception Phase
- The Inception Workshop Report
- Strategic Results Framework
- Project Management Arrangements
- Work Plan (detailed for Year 1-3)
- Budget for Year 1-3
- Terms of Reference (Staff, Committees)
- Monitoring and Evaluation Plan

Some facts and figures concerning the project are as follows:

PROJECT NUMBER	PIMS 2182
PROJECT NAME	Capacity Building for Implementation of Malaysia's National Biosafety Framework
DURATION	3 Years
IMPLEMENTING AGENCY	United Nations Development Programme
EXECUTING AGENCY	Ministry of Natural Resources and Environment
REQUESTING COUNTRY	Malaysia
ELIGIBILITY	Party to CBD on 24 June, 1994 Cartagena Protocol signed 24 May, 2000
GEF FOCAL AREA	Biodiversity
GEF PROGRAMMING FRAMEWORK	Enabling Activity (EA)

COSTS AND FINANCING (MILLION US\$)	
GEF Project	US\$ 911,389
Sub-Total	US\$ 911,38 0
Co-Financing	-
Government of Malaysia	US\$ 4,303,175
TOTAL PROJECT COST	US\$ 5,214,555

1 BACKGROUND

The Government of Malaysia (GoM) has identified biotechnology as one of the new income sources of the nation and envisioned it as the engine of growth for knowledge based economy in the country. The National Policy on Biological Diversity (NPBD) which was launched in 1998 calls for the sustainable utilization of biological resources among others through biotechnology. This was further augmented with the establishment of The National Biotechnology Policy in 2005. This Policy provides a guideline for a conducive environment for R&D and industry growth through leveraging on country's existing strength and capabilities. The government's emphasis on the agriculture sector is seen in the Biotechnology Policy where it is placed as the first thrust of the policy. Furthermore under the 3rd National Agriculture Policy for 1998-2010 (NAP3), where the main goal is to enhance food security and wealth creation through increased food production, biotechnology was identified as one of the five core technologies to transform the country into a highly industrialized nation by 2020. The attractive biotechnology incentives given to new biotechnology companies are one of the many efforts by the government to encourage biotechnology development in the country.

The Convention on Biological Diversity (CBD) is the first global treaty to provide a comprehensive framework that addresses all aspects of biodiversity. The Convention has three goals: the conservation of biodiversity, the sustainable use of the components of biodiversity, and the fair and equitable sharing of the benefits arising from the use of genetic resources. When crafting the Convention, governments recognized the potential of modern biotechnology. However, modern biotechnology must be developed and used with a regulatory system or framework to oversee, assess and manage the safety concerns of modern biotechnology. Malaysian together with Sweden played a key role in the early days (in 1991) of the CBD negotiation to introduce biosafety provisions. Biosafety is the shorthand for regulatory systems designed to ensure that applications of modern biotechnology are safe for human health, agriculture and the environment. In 1997, Malaysia demonstrated its commitment to biosafety and proactively set up the Genetic Modification Advisory Committee (GMAC) to formulate the National Guidelines on the release of genetically modified organism (GMOs) into the environment.

On 29 January 2000, the Conference of the Parties (COP) to the CBD adopted a supplementary agreement to the Convention known as the Cartagena Protocol on Biosafety (CPB). The Protocol seeks to protect biological diversity from the potential

risks posed by living modified organisms (LMOs) resulting from modern biotechnology. It establishes an advance informed agreement (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory.

Malaysia signed the CPB in the year 2000. Malaysia ratified the Protocol on the 3rd of September, 2003 and its entry into force was on the 2nd of December, 2003. Malaysia's recently passed Biosafety Act (11th July, 2007) states that before LMOs or its products can be imported, prepared, placed in the market, shall go through GMAC for scientific assessment before its approval by the National Biosafety Board (NBB). These LMOs will have to be exhaustively tested by the developer, independently evaluated for safety by scientists or experts in nutrition, toxicology, allergen city and other aspects of food science before approval can be obtained. It will also have to comply with the Ministry of Health's labeling provision that's being formulated.

1.1 Project Background

Under the Act, the Ministry of Natural Resources and the Environment (NRE) is to establish a National Biosafety Board (NBB) as the national focal point on biosafety to implement and enforce the Biosafety Act. NRE and other government agencies are ill equipped to successfully implement the Biosafety Act as there are insufficient capacities in risk assessment and risk management, administrative and regulatory implementation. At present, GMAC assists the Ministry of NRE on Biosafety matters. Additionally, little attention seems to have been given to the study of the socio-economic impacts of risks and the potential adverse effects on biotechnology on the environment. This project will help Malaysia build capacity to undertake these tasks as well as to build channels for information dissemination and public participation. For effective implementation of the Biosafety Act, and to fulfill the obligations under the CPB for transboundary movement of LMOs, customs officials must have full knowledge of the LMOs that will be crossing the country's national boundaries. This will again require capacity building in LMO detection among these enforcement officers.

The Project Brief for this ***Support to Capacity Building Activities on Implementing the Cartagena Protocol on Biosafety*** in Malaysia was approved in 2002 but the preparation and finalization of this Project Document was delayed because the tabling of the Biosafety Bill to the Malaysian Cabinet was delayed as the inter-ministerial

consultation on the Bill took more time than expected. The inter-ministerial consultations, an integral component in the process of drafting a piece of legislation on a subject matter which is new and cross-sectoral in nature had to be done effectively with full participation of all relevant ministries. Moreover, in 2004 a cabinet reshuffle saw some delay in finalizing the Project Document as the former Ministry of Science, Technology and the Environment was split into two separate ministries i.e. Ministry of Science, Technology and Innovations and Ministry of Natural Resources and Environment which will be the executing agency of this project.

1.2 Project Goal and Objectives

The overall goal of this project is to assist Malaysia to fully implement the obligations under the Cartagena Protocol related to the transboundary movement of LMOs. This includes the assessment, management and long term monitoring of the risks to the sustainable use of biodiversity and to human health potentially posed by the introduction of LMOs.

The objective of this project is that at the end of the three, there will be sufficient capacity in the country and effective coordination between the responsible agencies to assess and manage risks associated with the transboundary movement of LMOs. This will be achieved through the strengthening of the national biosafety framework with the necessary regulations, enhanced technical capacity and enforcement and monitoring capacities as well as a well managed information and coordination network.

1.3 Strategy

This 3 year project will assist in the development of a National Biosafety Framework. This project will enable Malaysia to effectively implement the newly passed Biosafety Act while implementing CPB obligations. Since Malaysia lacks experience in the area of Biosafety and given the fact of the infancy of the development of home grown of modern biotechnology external assistance to enhance capacity is much needed. The Global Environment Facility (GEF) intervention would complement baseline activities in Malaysia by ensuring that key required capacities for implementation of the CPB would be developed. This project is perfectly in line with the GEF strategy on biosafety.

1.4 Project Components

The main project components of this project to achieve the objectives are

- To establish legal and regulatory framework that permits the effective evaluation
(Component 1)
- Enhance scientific, socio-economic and institutional capacities for risk assessment
(Component 2)
- Increase capacity for developing and implementing a risk management programme
(Component 3)
- Develop capacity for long-term regime building maintenance
(Component 4)
- Develop institutional coordination and sharing of information
(Component 5)
- Raise public awareness relative to the transboundary movement of LMOs and promote participation of stakeholders
(Component 6)

1.5 GEF Resources Will Cover the Following Activities

- i) Cross-project learning with the other UNDP and UNEP capacity building demonstration projects by NBB staff
- ii) Short courses for lawmakers and policy decision makers in order that these key personnel can integrate the obligations under the Biosafety Act into the existing legal framework and put in place mechanisms to strengthen the coordination of the existing implementation and monitoring capacity of different government agencies;
- iii) Support and implementation of training activities to the representative of different ministries and the Customs Board in the field of LMOs identification, AIA procedures and RM;
- iv) Producing those manuals for private companies, which detail their obligations under the Biosafety Act.

- v) Building scientific capacity to monitor longer-term impacts on environment, human health and biodiversity through a risk management programme;
- vi) Setting up a biosafety portal and maintaining the database for increasing public awareness and wider participation. It is to be linked to the Biosafety Clearing House containing the information required by the CP; and
- vii) Complementing the Government efforts in preparing educational materials.

1.6 Intended Outputs

- Effectively implemented legal framework on biosafety
- Enhanced scientific, socio-economic and institutional capacities for risk assessment
- Increased capacity for developing and implementing a risk management programme
- Developed capacity for long- term operation and maintenance
- Improved information sharing and coordination between institutions and agencies
- Increased public awareness on biotechnology and biosafety

1.7 Expected Outcomes

- Enhanced management capacity at national level;
- Implementation of the national risk management regime;
- Enforcement of laws and regulations under the Biosafety Bill;
- Better coordination between different enforcement agencies;
- Better cooperation and partnerships between public and private sectors and civil society;
- Increased capacity for focused research in biosafety;
- Increased capacity in risk assessment, for implementation and enforcement of a national risk management programme, as the officers trained under this proposed project would be able to train others in their respective fields; and
- Increased awareness and understanding on biosafety issues among government officials and policy makers as a result of the capacity building activities.

2 PROJECT MANAGEMENT ARRANGEMENTS

Government of Malaysia

2.1 The National Steering Committee

The National Steering Committee (NSC) will review the programme on a quarterly basis. Also, each member of the NSC is expected to promote awareness of the project as well as biosafety issues in general within his/her agency; and facilitate consultations within their agency's jurisdiction. The TOR for NSC is attached under **ANNEX 4**. The NSC will be chaired by the Secretary-General, Ministry of Natural Resources and Environment.

2.2 National Executing Agency

The NRE will take charge of implementing the project, adhering to UNDP rules and procedures for national execution. Its responsibilities include; -

- Managing the resources allocated to the project to achieve the expected results and planning financial disbursements, in accordance with the work plan, and the project document;
- Maintaining an up-to-date accounting system that contains records and controls to ensure the accuracy and reliability of financial information and reporting
- Recording the receipt and disbursement of UNDP funds and verifying that disbursements do not exceed the available funds or the amount allocated to each approved budgetary category

In addition to the above, NRE will provide the following in-kind contribution:

- The National Project Director (NPD), whose terms of reference (TOR) is provided in **ANNEX 5**
- Appropriate officers to be attached as counterparts to the consultants
- Office facilities for consultants
- Access to all relevant data and information required to undertake the study;
- Use of office support facilities (e.g. computers, fax, stationery, Photostat machine, telephone, local transport), and secretarial support; and facilities for convening meetings.

2.3 Task Force / Working Groups

Task force or Working groups will be formed for the 6 components of the project. The members of the tasks forces or working groups will be stakeholders from relevant sectors. These task forces or working groups will assist in the assessment, development and implementation of the various indicative activities identified in the Strategic Results Framework (**ANNEX 1**). Regular consultative meetings of the tasks forces or working groups will be held for the smooth implementation and progress monitoring based on the set milestones of these activities. Through this process, national ownership, commitment and participation from all relevant stakeholders will be realized for an effective, transparent and unbiased management and implementation of the project activities. The TORs of these tasks forces or working groups will be prepared as the groups are formed.

2.4 Project Team

A Project Team will be created under NRE to administer the project. The unit will take charge of overall project management and co-ordination among different agencies. The Team will prepare work plans, budgets, and TOR for sub-contractors and consultants, and will be responsible for maintaining financial accounts and records according to UNDP guidelines for nationally executed projects. The Project Team will comprise one National Project Coordinator (NPC) and a Project Assistant (PA) whose TORs are attached as **ANNEX 6** and **ANNEX 7**, respectively. TORs for consultants will be developed later with the assistance of UNEP.

2.5 Project Management Unit (PMU)

The PMU within NRE was set up to provide accountability in the implementation of the project. It consists of the NPD who will chair the PMU, the UNDP Project Manager and the Project Team. The PMU shall meet once in 2 months and as and when the need arises.

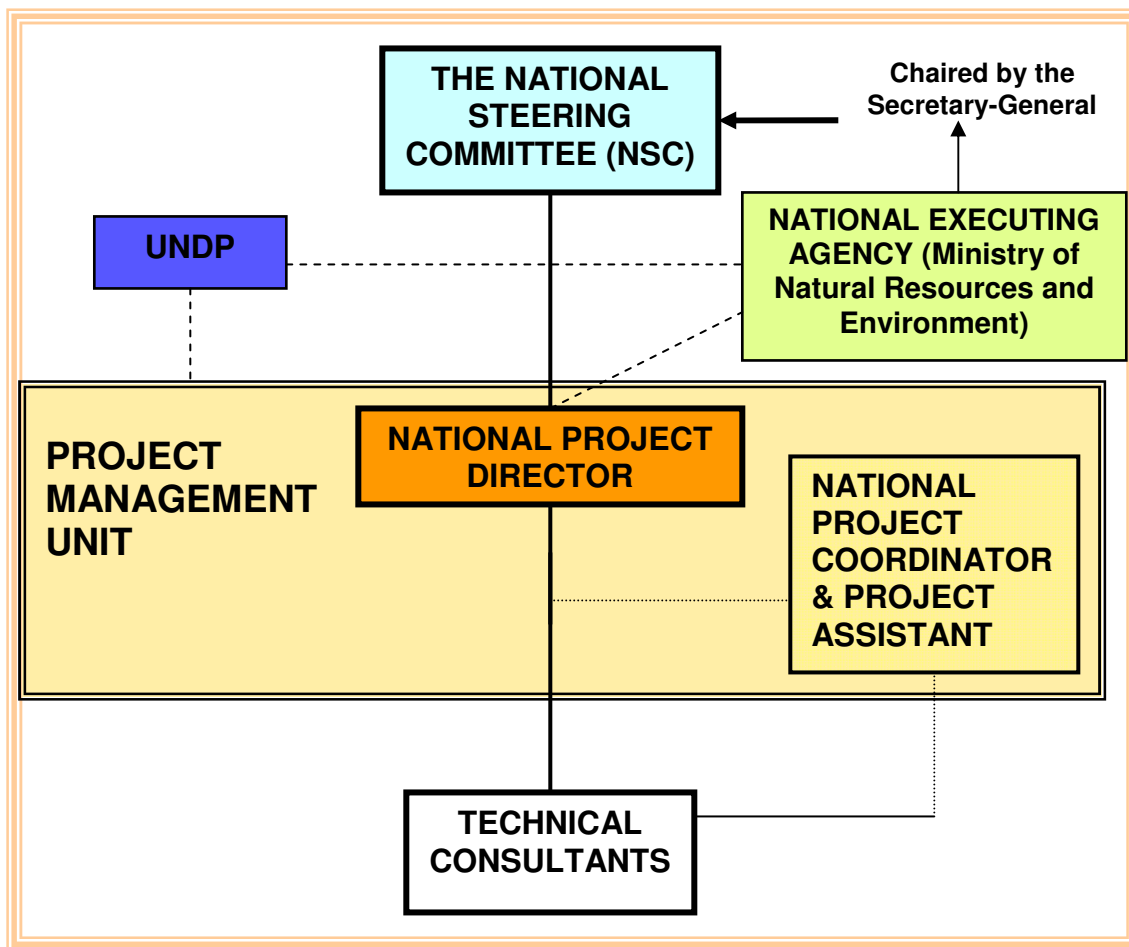
UNDP

UNDP Resident Representative ensures that the UNDP country office has an internal control system that allows it to monitor effectively the financial activity of the project and to support and monitor the progress towards achieving results. UNDP Malaysia may assist with direct payments to other parties for goods and services provided to the

project. In this connection, the government executing/implementing agency will forward to the UNDP a standard form “Request for direct payment”, duly completed and signed. In addition, UNDP Malaysia may provide the following services, as per the letter of agreement with GoM:

- (a) Identification and recruitment of project personnel;
- (b) Identification of training activities and assistance in carrying them out; and
- (c) Procurement of goods and services.

FIGURE 1 THE MANAGEMENT PROJECT STRUCTURE



2.6 Project Work Plan

The project is expected to be completed in 36 months, beginning 15th March 2007. The implementation of the project can be divided in 6 stages in accordance with the main project outputs. Table 1 highlight the overall project schedule and **Annex 5** is the detailed work plan describing timeline for each activity.

Table 1 Overall Project Schedule

Component	Year 1				Year 2				Year 3			
	I	II	III	IV	I	II	III	IV	I	II	III	IV
1. Strengthening the legal and regulatory framework	←			→	←			→	←			→
2. Building capacity in risk assessment	←			→	←			→	←			→
3. Building capacity in risk management	←			→	←			→	←			→
4. Building capacity for LT regime maintenance	←											→
5. Improving institutional coordination and information sharing	←											→
6. Increasing stakeholder awareness and participation	←											→
7. Project Management	←											→
8. Monitoring and Evaluation												←→

2.7 Project Budget

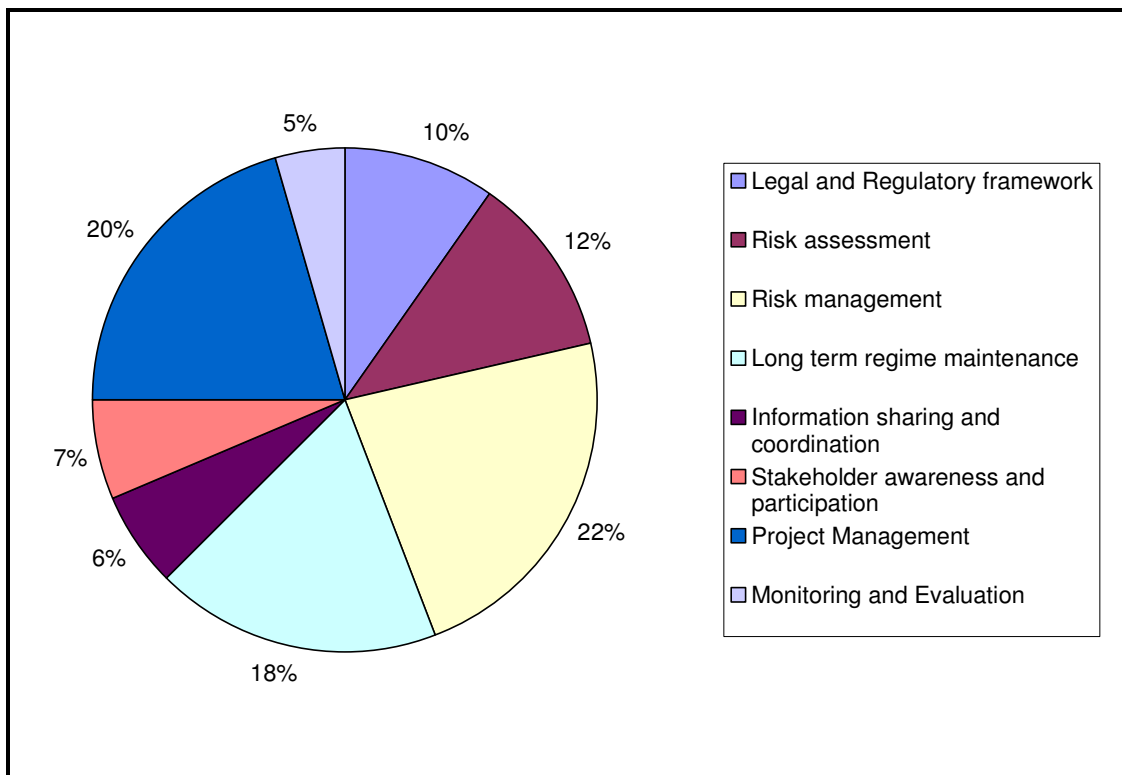
GEF provides funds for project team (NPC and PA) personnel costs including their allowances and operating costs such as workshops, training, printing, equipment, etc., totaling at USD 911,380. In-kind contribution from GoM totaling at USD 4,303,175 is for office facilities and administrative expenditures including cost of salary, domestic travel and allowances for all Government personnel involved in the project.

Table 2 shows the summary project budget to each output over the implementation period. Detailed budget is shown in **Annex 6**

Table 2 Summary of Project Budget

Component	GEF	GoM	Total
Legal and Regulatory framework	89,375	682,890	772,265
Risk assessment	105,505	1,423,906	1,529,411
Risk management	208,500	1,087,650	1,296,150
Long term regime maintenance	165,700	168,000	333,700
Information sharing and coordination	55,600	72,000	127,600
Stakeholder awareness and participation	59,700	846,729	906,429
Project Management	185,368.70	22,000	207,368.70
Monitoring and Evaluation	41,631.30	0	41,631.30
TOTAL	911,380	4,303,175	5,214,555

FIGURE 2 GEF FUNDING ACCORDING TO THE DIFFERENT COMPONENTS OF THE PROJECT



2.8 Monitoring and Evaluation

The standard monitoring and evaluation procedures required for UNDP/GEF projects are followed.

Quarterly Operational Report (QoR)

This is an approximately 100-word summary of the project’s substantive and technical progress towards achieving its objectives prepared by the NPD. The summaries are reviewed and cleared by UNDP Malaysia before being sent to the UNDP/GEF Regional Coordinator.

Budget Revision

An annual revision of the budget prepared by the Project Coordinator is mandatory and must be completed by **10 June**. This is to reflect the final expenditures for the preceding

year and to enable the preparation of a realistic plan for the provision of inputs for the current year. It needs to be approved by the Resident Representative or Officer-in-Charge and the UNDP/GEF Regional Coordinator. Other budget revisions may be undertaken as necessary during the course of the project.

Final Independent Evaluations

Both evaluations are undertaken by an independent evaluation team, in accordance with UNDP procedures and specific GEF requirements. TOR will be developed by UNDP Malaysia with input from UNDP/GEF, the PSU and the executing agency. It focuses on relevance, performance (effectiveness, efficiency and timelines), issues requiring decisions and actions, initial lessons learnt about project design, implementation and management as well as identifies early signs of potential impact and sustainability of results.

Annual Project Report and Project Implementation Review (APR/PIR)

The APR/PIR is prepared by PMU and may be completed and submitted via UNDP-Malaysia to the UNDP/GEF Regional Coordinator at any time, so long as it covers the July-June GEF reporting period. It may be used in the NSC meeting or any other review by executing agency

Budget

An overall budget of USD41, 631.12 is estimated for Monitoring and Evaluation process by UNDP. This includes USD20, 000 for independent consultants for final evaluation and UNDP's ISS. This allocation, although fairly limited, will be sufficient to undertake acceptable independent evaluations using evaluation capacity available within the immediate region.

3. ACTIVITIES IN THE INCEPTION PHASE

3.1 Project Start-up

The project was set up with the establishment of project office in CEMD, NRE on the 2nd January, 2007 with the hiring of the project assistant. The National Coordinator was recruited and commenced activities on the 15th March 2007.

A meeting with UNDP Project Manager, Project Representative from Ministry of Natural Resources and Environment and Project Assistant was held on the 22nd March 2007 to discuss the operationalisation of the project.

During the inception phase, a total of four project team meetings were held to discuss matters relating to work plan, project budget, project reporting and management, inception workshop.

It was also during this phase that the Malaysian National Biosafety Bill was in the process of being read in the Parliament for the second and third readings. Various consultative and preparatory meetings were attended to assist the Ministry of Natural Resources and Environment in their efforts to have the draft bill tabled in Parliament in time. These consultative meetings were held by the Ministry with certain stakeholders to meet and address their concerns on certain issues of the draft Bill. The Malaysian National Biosafety Law was passed by the Malaysian House of Representatives on the 27th of June 2007 and finally by the Senate on the 11th July, 2007.

Third National Project Coordinators' Meeting on UNEP-GEF Biosafety Projects was held in Tanzania from 28th May – 2nd June, 2007. UNEP invited National Project Coordinators from other UN agencies and international organisations that were also implementing Biosafety projects to attend the meeting. Lessons and experiences in implementing the Biosafety projects gained from UNEP facilitated countries at this meeting will be of tremendous assistance for Malaysia to implement the Biosafety Project more effectively. At this meeting, discussions were held with the UNEP's Regional Coordinator for Biosafety in Asia to explore the involvement of UNEP in the implementation of the Malaysian Biosafety project. UNEP was in total support of this technical collaboration.

The Fourth ASEAN GMO Testing Network meeting was held in Vietnam from the 21st - 23rd May where the main concern was the efforts needed to build capacity in this very important area of risk assessment. Malaysia is playing a lead role in this as the laboratory in the Chemistry Department under the Ministry of Science, Technology and Innovation (MOSTI) has been accredited by EU to be the ASEAN reference lab for GMO testing. Efforts to look at setting up a service facility for the ASEAN region for the testing and certification of GMOs were also discussed with Malaysia playing a key role in this.

3.2 Inception Workshop

The inception workshop was held on the 19th July, 2007 at the Equatorial Hotel, Bangi - Putrajaya. A total of 97 participants from various sectors including government agencies, academia and research institutions, NGOs and private sector attended the workshop.

The objective of this workshop was to serve as an introductory session on the NRE/UNDP/GEF Biosafety Project to all national stakeholders and to provide them with an opportunity to comment and recommend activities of the project and identify respective roles and involvement.

The workshop was officially opened by Hon. Dato' S Sothinathan, Deputy Minister of Natural Resources and Environment (NRE). The workshop started with welcome notes from Dr Lian Kok Fei, Undersecretary of the CEMD, Ministry of NRE and Mr Hari Ramalu Ragavan, the UNDP Biosafety Programme Manager. After which, a press conference was held to raise awareness and publicise the objectives and activities of the project. Details of the event can be found in **Annex 8**.

The Plenary session comprised of four speakers. Mr K. Nagulendran from the Ministry of NRE, who is also the NPD of this project, gave a comprehensive overview of the CPB and Biosafety activities in Malaysia and the importance for building capacity for the implementation of the new Biosafety Act.

The capacity building project for the successful implementation of the Biosafety Act was explained in greater detail by National Project Coordinator who highlighted the objectives and project components and its related expected outputs and activities. Mr Hari Ramalu

Ragavan, the project manager highlighted the overall mechanism of implementation, monitoring, reporting and reviewing structure for this project.

The Plenary session ended with the presentation of Dr Low Fee Chon from UNEP Bangkok who shared her technical experience in the implementation of similar projects in Africa, Eastern Europe as well as Asia. She highlighted some of the issues and challenges that were faced by the projects of which she was the technical advisor and presented precautions and issues for consideration when implementing this project.

The participants were then divided into 6 groups according to their respective sectors (2 government, Research Institutes, Non-governmental Organisations, Private Sector and Academia) and given the opportunity to scrutinize the project Strategic Results Framework (Appendix A of the Inception report **Annex 8**) and give their inputs on how best to improve the implementation of the project. Each group presented their suggestions, comments and critical views to the whole workshop and these have been incorporated in the Strategic Results Framework (**Annex 1**).

4.0 WORK PLAN

The implementation of this project will be carried out according to the 6 components identified. Consultant(s) will be identified and appointed to assist in the assessment of the work plan as well as the implementation process. A multi stakeholders' participatory approach will be taken in the formation of task forces or working groups in which the stakeholders will be from relevant sectors. These task forces or working groups will assist in the assessment, development and implementation of the various indicative activities identified in the Strategic Results Framework (**Annex 1**). Consultative meetings of the task forces or working groups will be held frequently for the smooth implementation of these activities and also to monitor progress by the milestones set out. It is envisaged that through this process, national ownership, commitment and participation from all sectors, be it government, private or NGOs will be more evident. In order to assist Malaysia implement and enforce the National Biosafety Act to its maximum effectiveness, a transparent and unbiased approach will be adopted for overall management and implementation of the capacity building activities of this project.

4.1 Inception

The National Steering Committee will review the activities outlined in the Inception Report according to its effectiveness and relevance to the overall objectives of the project. The budget will be aligned according to the activities formulated.

4.2 Amendments on the Strategic Results Framework

Based on the comments, suggestions and ideas presented by the 6 breakout groups the strategic results framework was amended and presented as **Annex 1**. The amendments are summarized below.

Component 1

To establish legal and regulatory framework that permits the effective evaluation

- It was suggested to prioritize the activities and have the formulation of regulations and guidelines first. As such 2 output targets were added on to have relevant stakeholders come together to formulate guidelines, SOPs and regulations for research, IBC, GMO release. These are indicated in **Annex 1 as 1.1 and 1.2**.
- The suggestion to remove risk management training to be included for enforcement officers was not accepted as it is important for these officers to know how to manage or mitigate risks if it were to occur at ports of entry, warehouses etc. The training modules will be tailored according to the needs and requirements of the stakeholders taking part in these activities.
- The suggestion to include investigation and inspection skills/procedures as well proper procedures for sampling to be included in the workshops for enforcement officers was taken into consideration and is indicated in **1.4.1 of Annex 1**
- The suggestion to include IBC members other than GMAC members for hands on workshop on handling applications was included. This is indicated in **1.5 of Annex 1**
- The inclusion of media, social scientists, religious bodies in workshops on the administration and implementation of the Biosafety Act is indicated in **1.2 of Annex 1**
- The comment on the application process being more relevant than the application forms and should be included as one of the workshop components was added on and it is indicated in **1.2.1 of Annex 1**

- The training of biosafety officers that serve in Institutions and Universities as part of the IBC set up was highlighted and taken up in **1.3 of the Annex 1**
- There were various comments and suggestions on the study tours by GMAC members to countries that had an established biosafety administrative structure.
 - Learn from the EU, Australia and Japan – these countries to visit will be taken into consideration when planning the visits
 - Lessons learnt should be made public – their experiences learnt will be documented **1.6.1 of Annex 1**
 - Add on emergency response plans to be learnt from other countries – details as such will be part of the objectives of the study tours
 - Invite experts from overseas to share their experiences- an option that was added on as part of the activities in **1.6.1 Annex 1**
 - Delete the study tours completely -suggestion not accepted as the majority felt that the study tours will be of benefit to finally have a strong pool of regulators which in turn can train future regulators
- Some of the suggestions were too detailed to be in the strategic results framework but will be taken into consideration when training and workshop modules are devised for the various stakeholders.

Component 2

Enhance scientific, socio-economic and institutional capacities for risk assessment

- The suggestion to include socio economic, ethical and environmental impacts in the training modules was taken **2.1.1. Annex 1**
- Training on writing field release dossiers has been included **2.3.1 Annex**

Component 3

Increase capacity for developing and implementing a risk management programme

- Suggestions to include the following were taken
 - Aquatic plants **3.1. Annex 1**
 - Change from post release land use to post release environmental impact **3.1.1 Annex 1**
 - Fish and animals **3.2 Annex 1**
 - Plants and animals used for bio-pharming **3.4 Annex 1**

Component 4

Develop capacity for long-term regime building maintenance

- Suggestion to include researchers from universities was added to **4.1 Annex 1**
- Suggestion to delete visit by senior scientists to centre's of excellence prior to purchasing of equipment software was taken and the money used to purchase equipment for new and existing labs **4.1.1. Annex 1**
- Suggestion to delete workshop for food and feed safety was taken as it can be covered in **2.1 of Annex 1**
- Suggestion to delete technical visits by 2 members of the NBB was taken as the purpose of the visit was not relevant and important for the overall objective of implementing the biosafety Act

Component 5

Develop institutional coordination and sharing of information

- Suggestion by industry to identify stakeholders (private sector, NGOs) before improving information sharing can be delegated to the relevant agencies before these workshops are carried out. **5.1 of Annex 1**
- The suggestion to have the database that is linked to the BCH be uniform and according to international standards was taken **5.2. and 5.3 of Annex 1**
- Suggestion to include status of application and other relevant information but privacy and confidentiality to be taken into consideration was taken **5.4 of Annex**. This database can be accessed by the public as well.

Component 6

Raise public awareness relative to the transboundary movement of LMOs and promote participation of stakeholders

- Suggestion to have an interactive website and a permanent communications officer appointed under the NBB was taken **6.1 of Annex 1**
- Training for NBB and not for IT specialists was also taken **6.1.1 of Annex 1**

- Training workshops on risk communication to include MOE, MITI, MOI and religious bodies was taken **6.2 of Annex 1**
- The need to set up a review committee to vet the information to be disseminated will be taken into the operating procedures of this project.
- The suggestion to have road shows to create stakeholder awareness is good and will be considered if budget permits **6.5 of Annex 1**
- Suggestion to have biosafety incorporated into secondary school curriculum included **6.4 of Annex 1**

5.0 Challenges Ahead

Malaysia has been carrying out capacity building activities in Biosafety since 1997. However these activities are spread thinly across various institutes and universities. Many of these activities were not carried out with an overall plan and objective in sight. This resulted in capacities being built among many people of various levels on understanding of the subject matter i.e. Biosafety and thus with diluted results. There was no sustainability of these projects as well as the efforts.

The huge task ahead of this project to support capacity building activities to implement the Biosafety law will have to attempt to take stock of these past activities and move ahead with planning of a set of activities/workshops that is more cohesive in nature, emphasizing the importance of continuity of both the human resource factor as well the sustainability of various stakeholders.

However, before these activities can take off, the level of understanding of the various stakeholders on biosafety and the Biosafety Framework will have to be enhanced in order for the participants to fully appreciate and assimilate the contents of these workshops.

Another challenge ahead of this project is the funds awarded to this project to fully implement all the planned activities is less than what was allocated earlier due to the appreciating Malaysian ringgit. The government must also take stock of this and have proactive measures in place well in advance.

Frequent staff movement or organizational re-structuring within the implementing agencies and departments during the course of this project might result in discontinuity and interested participation. However, the project team will endeavor to see that this be minimized and more importantly for the implementing agency to ensure the sustainability of Biosafety activities.

ANNEX 1 Strategic Results Framework

INTENDED OUTPUTS	OUTPUT TARGETS	INDICATIVE ACTIVITIES	MILESTONE	INPUTS
<p>1. Effectively formulated and implemented legal framework on biosafety</p>	<p>1.1 Workshops on the administration and implementation of the Malaysian Biosafety Act where research is concerned for relevant stakeholders organized. Members from the public and private biotechnology research sectors, academia, regulators, invited to formulate the appropriate guidelines and regulations.</p>	<p>1.1.1 Organise a series of workshops to:</p> <ul style="list-style-type: none"> • Formulate guidelines and regulations for the establishment of Institutional Biosafety Committee for Universities, Research Institutes and commercial entities conducting research on GMOs. • Formulate guidelines, regulations and Standard Operating Procedures (SOP) for research on GMOs in contained trials and laboratories 	<p>1.1.1.1 Guidelines and SOPs formulated, certified, published and downloaded on official website</p>	<ul style="list-style-type: none"> • Workshop costs • Consultants cost • Reviewers cost
	<p>1.2. Consultative workshops on the administration and implementation of the Malaysian Biosafety Act for all stakeholders organized. Members from the public and private biotechnology sectors, academia, researchers,</p>	<p>1.2.1 Organise a series of consultative workshops to:</p> <ul style="list-style-type: none"> • Review forms and the whole process for notification on GMO research • Review proposed application forms, application process 	<p>1.2.1.1 Notification and approval process and regulations, including all necessary forms formulated and downloaded onto official website.</p>	<ul style="list-style-type: none"> • Workshop costs • Consultants cost • Reviewers cost

	<p>regulators, policy makers, media, politicians, religious groups, social scientists and NGOs invited to formulate regulations</p> <p>1.3 Training of biosafety officers to serve in research institutions, universities and other organizations involved in GMO research, release and commercialization</p>	<p>and approval processes for release of LMOs (R&D trials and for Commercial purpose)</p> <ul style="list-style-type: none"> Review process for exemption, Identify products to be exempted from AIA and the appropriate application regimes Review the utility of a “User Guide in making an application” for a user-friendly application process <p>1.3.1 Organise workshops for biosafety officers that will serve in their respective IBCs to:</p> <ul style="list-style-type: none"> Review research proposals on GMO research to check for proper risk assessment and management procedures are in place for contained 	<p>1.2.1.2 Exemption list and process for exemption made available on official biosafety website</p> <p>1.2.1.3 User-guide produced and made available as hardcopy and on official biosafety website</p> <p>1.3.1.1 Fully functional and operational IBCs formed throughout the country</p>	<ul style="list-style-type: none"> Workshop costs Consultants cost Reviewers cost <ul style="list-style-type: none"> Workshop costs Consultants cost Reviewers cost <ul style="list-style-type: none"> Workshop costs Consultants cost
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	<p>1.4 A “training the trainers” workshop for 50 enforcement officers from different ministries and the Customs Board to regulate import of LMOs at points of entry into the country organized. Recognition and procedures to handle unapproved GMOs will also be included</p> <p>1.5 Workshop on handling applications for 50 including GMAC members and other regulators organized.</p> <p>1.6 Study tours of GMAC members, (in groups of 2-3) to various foreign countries which have an established biosafety institutional and administrative structure undertaken.</p>	<p>use</p> <p>1.4.1 Organise a special workshop for enforcement officers to acquire basic knowledge in:</p> <ul style="list-style-type: none"> • Investigation skills or procedures • LMO identification and sampling procedures • Documentation • AIA procedures • Risk management <p>1.5.1 Organize “Hands-on” workshop on handling requests and applications for release of LMOs, using real dossiers and administered under the proposed Biosafety Act</p> <p>1.6.1 GMAC members to visit similar biosafety regulatory bodies to:</p> <ul style="list-style-type: none"> • Learn the implementation of their biosafety framework • Be updated on best practices in biosafety 	<p>1.4.1.1. Trained enforcement officers from various ministries operating at the various points of entry</p> <p>1.5.1.1 The newly appointed GMAC members and relevant regulators will be familiarized with the various types of applications.</p> <p>1.6.1.1 A core group of scientific regulators will be formed for with enhanced expertise in assessing applications and also to train</p>	<ul style="list-style-type: none"> • Workshop costs • Consultants cost <ul style="list-style-type: none"> • Workshop costs • Consultants cost <ul style="list-style-type: none"> • Study tour costs
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	<p>1.7 Cross project learning study tours and international meetings on biosafety related issues attended by policy makers, lawmakers and regulators.</p>	<ul style="list-style-type: none"> • Share experience with counterparts abroad • Experiences should be documented for present future members to gain from <p>1.7.1 Key policy makers, lawmakers and regulators to attend international meetings and study tours on biosafety to:</p> <ul style="list-style-type: none"> • Strengthen legal mechanisms by identifying gaps • Continuously improve regulations and guidelines • Be familiar with international best practices • Cross-project learning with other UNDP and UNEP capacity building projects by NBB staff. 	<p>future regulators</p> <p>1.7.1.1 Better understanding of experiences of other countries in Biosafety, which can be useful for national implementation as well as further improvement of the regulations and guidelines</p>	<ul style="list-style-type: none"> • NRE and NBB will identify relevant meetings • Mission costs
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2. Enhanced scientific, socio-economic and institutional capacities for risk assessment	2.1 Technical training workshops including quantitative detection of GMO and products for 60-80 scientists, regulators and scientists & technicians from the GMO Detection Laboratories organized	2.1.1 Organize a series of workshops for: <ul style="list-style-type: none"> • GMO & products detection • Quantitative measurement for the presence of GMO & products in food, feed and others. • Food & feed safety assessment • Risk assessment • Risk management • Up-grading skills and techniques • Environmental impact • Socio economic and ethical aspects 	2.1.1.1 GMO detection labs will be fully functional and operational manned by experienced technician and scientists to fulfill regulatory requirements. Certified detections will be published and made available on official biosafety website	<ul style="list-style-type: none"> • Workshop costs • Consultants cost • Reviewers cost
	2.2 Workshop on long-term monitoring for 60 scientists, sociologists, environmentalists, regulators, private industry and NGOs to evaluate the impact of the release of LMOs into the environment organized.	2.2 .1 Organize a workshop for: <ul style="list-style-type: none"> • Monitoring, reviewing and reporting of effectiveness of risk management • Assessment methods • Long term impact analysis • Cost benefit analysis 	2.2.1.1. Environmental impact assessment can be carried out by trained scientists	<ul style="list-style-type: none"> • Workshop costs • Consultants cost • Reviewers cost
	2.3 Technical workshop on preparation of dossiers for	2.3.1 Organize a series of workshop on	2.3.1.1. Well written dossiers for field	<ul style="list-style-type: none"> • Workshop costs • Consultants cost

	<p>field release of LMOs for 60 scientists and academicians from R&D institutions and universities organized.</p> <p>2.4 Technical workshop on food/feed safety assessment of GMF for 60 food scientists, Health officials, regulators and academicians from R&D institutions and universities organized.</p>	<p>preparation of dossiers for field release application:</p> <ul style="list-style-type: none"> • Biology of parental organism • Intended use • Receiving environment <p>2.4.1 Organize a workshop on:</p> <ul style="list-style-type: none"> • Food/feed safety assessment methods • Validation of safety Data • Long term impact analysis 	<p>release will be assessed by regulators</p> <p>2.4.1.1. Fully certified methods for safety assessment of GMOs used as food and feed documented</p>	<ul style="list-style-type: none"> • Reviewers cost • Workshop costs • Consultants cost • Reviewers cost
<p>3. Increased capacity for developing and implementing a risk management programme</p>	<p>3.1 Technical training workshops for between 80-120 researchers Including reps from IBCs), academicians and regulators on risk management of GM crop plants (annuals & aquatics) organized.</p>	<p>3.1.1. Organize a series of workshops for:</p> <ul style="list-style-type: none"> • Risk identification • Risk evaluation • Risk mitigation • Emergency response plan • Damage control plan for residue • Post release Monitoring • Post release environmental impact 	<p>Well documented risk assessment management procedures for all kinds of GMOs produced to be used by relevant stakeholders conducting GMO research or regulating GMOs</p>	<ul style="list-style-type: none"> • Workshop costs • Consultants cost • Publication costs • Reviewer costs

	<p>3.2 Technical training workshops for 80-120 researchers, academicians and regulators on risk management of GM microbes, fish and animals organized.</p> <p>3.3 Technical training workshops for 60-80 researchers, academicians and regulators on risk management of GM trees (perennials) organized.</p> <p>3.4 Technical training workshops for 60-80 researchers, academicians and regulators on risk management of GM plants, microbes and animals used for bio-pharming organized.</p>	<p>3.2.1 Organize a series of workshops for:</p> <ul style="list-style-type: none"> • Risk identification • Risk evaluation • Risk mitigation • Emergency response plan • Post release Monitoring <p>3.3.1 Organize a series of workshops for:</p> <ul style="list-style-type: none"> • Risk identification • Risk evaluation • Risk mitigation • Emergency response plan • Post release Monitoring <p>3.4.1 Organize a series of workshops for:</p> <ul style="list-style-type: none"> • Risk identification • Risk evaluation • Risk mitigation • Emergency response plan • Post release Monitoring 		<ul style="list-style-type: none"> • Workshop costs • Consultants cost • Publication costs • Reviewer costs <ul style="list-style-type: none"> • Workshop costs • Consultants cost • Publication costs • Reviewer costs <ul style="list-style-type: none"> • Workshop costs • Consultants cost • Publication costs • Reviewer costs
4. Developed capacity for long-term operation and	4.1 40-50 scientists and technicians to operate the GMO Laboratory	4.1.1 "Hands-on" training for scientists and staff in:	4.1.1.1 A certified manual on all standard	<ul style="list-style-type: none"> • Workshop costs • Consultants cost

<p>5. Improved information sharing and coordination between institutions and agencies</p>	<p>5.1 Workshop for 60-80 senior officers from government agencies, enforcement agencies and policy makers on the implementation and enforcement of the proposed Biosafety Act organized. Stakeholders from the private sector and NGOs to also be identified</p>	<p>5.1.1. Workshop to inform collaborating government agencies on the need for their assistance in order to implement and administrate the proposed Biosafety Act.</p>	<p>5.1.1.1 Proper and continuous information shared between all stakeholders.</p>	<ul style="list-style-type: none"> • Workshop costs • Consultants cost • Reviewer costs
	<p>5.2 Uniform and internationally accepted database which is linked to the Biosafety Clearing House(BCH) and other national government agencies, R&D institutions and the national biotechnology network (NBBnet) constructed and maintained</p>	<p>5.2.1 Training of Information Technology (IT) specialist to:</p> <ul style="list-style-type: none"> • Set up and maintain database • Link database to BCH 	<p>5.2.1.1. Databases set up with relevant information to be used in decision making process</p>	<ul style="list-style-type: none"> • Workshop costs • Consultants cost • Publication costs
	<p>5.3 30-50 officers from different enforcement agencies on data management trained</p>	<p>5.3.1 Training of IT specialists to:</p> <ul style="list-style-type: none"> • Set up and maintain individual database • Link these databases to NBB database 	<p>5.3.1.1 The formation of databases by certain stakeholders for use by all concerned, including public</p>	<ul style="list-style-type: none"> • Workshop costs • Consultants cost • Publication costs

	5.4 Workshop to share information from long-term monitoring results including cost-benefit analysis of releases of LMOs, status of applications for 60-80 scientists, sociologists, regulators, environmentalists, relevant govt. agencies, private industry and NGOs organized.	5.4.1 Training of government agencies on the use of BCH, including inputting data and accessing information	5.4.1.1 The relevance of BCH as a source of information to be made understood	<ul style="list-style-type: none"> • Workshop costs • Consultants cost • Publication costs • Reviewer costs
6. Increased public awareness on biotechnology and biosafety	6.1 Interactive website for NBB as a channel for public communication and participation constructed. A Communications officer to be appointed	6.1.1 Training for members of NBB on biosafety issues and identifying information to be included in website without breach of confidential business information (CBI).	6.1.1.1 NBB website constructed to be used as part of efforts for public awareness and participation in decision making process	<ul style="list-style-type: none"> • Workshop costs • Consultants cost
	6.2 Training workshop on risk communication to 120 – 150 policy makers from MOE, MOI, MITI, enforcement officers, scientists, media personnel, religious bodies and NGOs organized	6.2.1 Organize a workshop on explaining science to the public, to increase awareness on biosafety issues and Malaysia's international obligations	6.2.1.1 Level of public awareness on issues of biosafety increased so that public can made informed choices where GMOs are concerned	<ul style="list-style-type: none"> • Workshop costs • Consultants cost • Publication costs

	<p>6.3 Consumer education and public awareness (CEPA) programmes for all stakeholders conducted.</p> <p>6.4 Biosafety to be incorporated into curriculum at tertiary and secondary</p> <p>6.5 Stakeholders dialogue and feedback for 150 participants from industry, R&D institutes, universities, farmer groups, NGOs, etc. carried out</p>	<p>6.3.1 Produce education kits, flyers, posters, documentary films in different languages for different target groups on issues of biosafety.</p> <p>6.4.1 Dialogue and workshops conducted to assist the incorporation of biosafety modules into the tertiary and secondary school curriculum</p> <p>6.5.1 Organize a series of dialogue sessions with industry, R&D institutes, universities, farmer groups, NGOs to promote better understanding on biosafety matters. These can be in the form of road shows</p> <p>6.5.2 Conduct a survey on understanding of biosafety</p>	<p>6.3.1.1. Well documented articles, audio visual material produced in the 3 main languages for effective and wider dissemination of information on biosafety</p> <p>6.4.1.1 Incorporation of biosafety modules in tertiary and secondary school curriculum</p> <p>6.5.1.1. Survey conducted to assess public awareness and understanding on biosafety environment.</p>	<ul style="list-style-type: none"> • NRE and NBB prepare the materials in collaboration with professional media and promotional experts • Workshop costs • Consultants cost • Workshop costs • Consultants cost • Publication costs • Consultants cost • Survey costs
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ANNEX 2 BIOSAFETY PROJECT WORK PLAN

Outputs and Activities		Responsible Party	2007				2008				2009				2010			
			S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4
Output 1 Effectively formulated and implemented legal framework on biosafety																		
1.1	Organise a series of workshops to formulate guidelines for the establishment of Institutional Biosafety Committee	NRE				←→												
1.2	Organise a series of workshops to formulate guidelines and Standard Operating Procedures (SOP) for research on GMOs in contained trials and laboratories	NRE				←→												
1.3	Organise a series of consultative workshops to review forms and the whole process for notification on GMO research	NRE				←→												
1.4	Organise a series of consultative workshops to review proposed application forms, application process and approval processes for release of LMOs (R&D trials and for Commercial purpose)	NRE				←→												

Outputs and Activities	Responsible Party	2007				2008				2009				2010			
		S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4
Output 1 Effectively formulated and implemented legal framework on biosafety																	
1.5	Review process for exemption, Identify products to be exempted from AIA and the appropriate application regimes	NRE					←→										
1.6	Review the utility of a "User Guide in making an application" for a user-friendly application process	NRE					←→										
1.7	Organise workshops for biosafety officers that will serve in their respective IBCs to review research proposals on GMO research to check for proper risk assessment and management procedures are in place for contained use	NRE					←→										

1.8	Organise a special workshop for enforcement officers to acquire basic knowledge in 1. Investigation skills or procedures, 2 LMO identification and sampling procedures, 3 Documentation, 4.AIA procedures and 5. Risk management	NRE					←													
Outputs and Activities		Responsible Party	2007				2008				2009				2010					
			S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4		
Output 1 Effectively formulated and implemented legal framework on biosafety																				
1.9	Organize “Hands-on” workshop for GMAC members on handling requests and applications for release of LMOs, using real dossiers and administered under the proposed Biosafety Act	NRE				↔				↔				↔						
1.10	GMAC members to visit similar biosafety regulatory bodies to learn the implementation of their biosafety framework Be updated on best practices in biosafety	NRE				↔														

1.1 1	Organise workshops for biosafety officers that will serve in their respective IBCs to review research proposals on GMO research to check for proper risk assessment and management procedures are in place for contained use	NRE				←	→						←	→					
Outputs and Activities		Responsible Party	2007				2008				2009				2010				
			S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4	
Output 1 Effectively formulated and implemented legal framework on biosafety																			
1.1 2	Key policy makers, lawmakers and regulators to attend international meetings and study tours on biosafety to: <ul style="list-style-type: none"> Strengthen legal mechanisms by identifying gaps Continuously improve regulations and guidelines Be familiar with international best practices 	NRE				←	→												
Project monitoring and evaluation																			

Output 2. Enhanced scientific, socio-economic and institutional capacities for risk assessment																		
Outputs and Activities	Responsible Party	2007				2008				2009				2010				
		S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4	
Output 2. Enhanced scientific, socio-economic and institutional capacities for risk assessment																		
2.1	Organize a series of workshops for 60-80 scientists, regulators and scientists & technicians from the GMO Detection Laboratories	NRE					←	→					←	→				
2.2	Organize a workshop for 60 scientists, sociologists, environmentalists, regulators, private industry and NGOs to evaluate the long term impact of the release of LMOs into the environment & costs benefit analysis	NRE							←	→								
2.3	Organize a series of workshop on preparation of dossiers for 60 scientists and academicians from R&D institutions and universities	NRE					←	→					←	→				

2.4	Organize a workshop on food/feed safety assessment methods, validation of safety data and Long term impact analysis for 60 food scientists, Health officials, regulators and academicians from R&D institutions and universities	NRE																
Outputs and Activities		Responsible Party	2007				2008				2009				2010			
			S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4
3. Increased capacity for developing and implementing a risk management programme																		
3.1	Organize a series of technical training workshops for GM crop plants (annuals & aquatics) for between 80-120 researchers Including reps from IBCs), academicians and regulators on risk management of GM crop plants (annuals & aquatics)	NRE																
3.2	Organize a series of technical training workshops for GM microbes, fish and animals for 80-120 researchers, academicians and regulators on risk management of GM microbes, fish and animals	NRE																

3.3	Organize a series of technical training workshops for 60-80 researchers, academicians and regulators on risk management of GM trees (perennials)	NRE																
Outputs and Activities		Responsible Party	2007				2008				2009				2010			
			S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4
3. Increased capacity for developing and implementing a risk management programme																		
3.4	Organize a series of technical training workshops for 60-80 researchers, academicians and regulators on risk management of GM plants, microbes and animals used for bio-pharming workshops	NRE																
4. Developed capacity for long- term operation and maintenance																		
4.1	“Hands-on” training for 140-50 scientists and technicians to operate the GMO detection labs -Chemistry Dept, MOH, -MOA, East Malaysia, Universities & research institutes	NRE																

Outputs and Activities	Responsible Party	2007				2008				2009				2010			
		S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4
4. Developed capacity for long- term operation and maintenance																	
4.2	Organize workshops on long-term enforcement of food and feed safety for 60 enforcement officers, food scientists, food manufacturers and NGOs a workshop	NRE															
4.3	Organise workshop for 50 Legal Advisors from relevant Ministries and Principle Investigators from research institutes and universities on biosafety, IPR, international obligations and other the legal matters.	NRE															
Project monitoring and evaluation																	

Outputs and Activities	Responsible Party	2007				2008				2009				2010			
		S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4
5. Improved information sharing and coordination between institutions and agencies																	
5.1	Organise workshop for 60-80 senior officers from government agencies, enforcement agencies and policy makers on the implementation and enforcement of the proposed Biosafety Act	NRE															
						←————→											
5.2	Construct and maintain database which is linked to the Biosafety Clearing House(BCH) and other national government agencies, R&D institutions and the national biotechnology network (NBBnet)	NRE															
						←————→											
5.3	Training of 30-50 officers from different government enforcement agencies on data management and on the use of BCH, including inputting data and accessing information	NRE															
						←————→											

5.4	Training workshop of IT specialists to share information from long-term monitoring results including cost-benefit analysis of releases of LMOs, for 60-80 scientists, sociologists, regulators, environmentalists, relevant govt. agencies, private industry and NGOs	NRE																
Outputs and Activities		Responsible Party	2007				2008				2009				2010			
			S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4	S1	S2	S3	S4
6. Increased public awareness on biotechnology and biosafety																		
6.1	Training for members of NBB on biosafety issues and identifying information to be included in website without breach of confidential business information (CBI).	NRE																
6.2	Organize a workshop on explaining science to the public, to increase awareness on biosafety issues and Malaysia's international obligations	NRE																

6.3	Produce education kits, flyers, posters, documentary films in different languages for different target groups on issues of biosafety.	NRE						←		→								
6.4	Organize a series of dialogue sessions with industry, R&D institutes, universities, farmer groups, NGOs to promote better understanding on biosafety matters	NRE						←										

Project monitoring and evaluation

- S1 January- March
- S2 April- June
- S3 July – September
- S4 October – December

←————→ **Duration of activities**

ANNEX 3 Total Budget

Total Project Budget under GEF Financing

TOTAL PROJECT AND BUDGET										
Award ID: 00043797										
Award Title: PIMS 2182 BD EA: MAL: Biosafety										
Project ID:: 00051229										
Project Title: PIMS 2182 BD EA: Support to Capacity Building Activities on Implementing the Cartagena Protocol on Biosafety										
Executing Agency: Ministry of Natural Resources and Environment (MNR)										
	GEF Outcome/Atlas Activity	Responsible Party	Source of Funds	Atlas Code	ERP/ATLAS Budget Description/ Input	Amount (USD) Year 1	Amount (USD) Year 2	Amount (USD) Year 3	Total (USD)	Total (USD)
0	Project Management and Monitoring and Evaluation	Ministry of Natural Resources and Environment	GEF	71300	Local consultants	60,000.00	60,000.00	60,000.00	180,000.00	
				74500	Miscellaneous Expenses	1503.10	1695.80	2169.80	5368.70	
					Monitoring & Evaluation	7496.90	7304.20	23571.20	41,631.30	
					Sub-total	69,000.00	69,000.00	89,000.00	227,000.00	
			GOM	71300	Local Consultant	22,000.00			22,000.00	
					Sub-total	22,000.00			22,000.00	
1	Effectively implemented legal framework on biosafety	Ministry of Natural Resources and Environment	GEF	71200	International consultants	27,700.00			27,700.00	
				71600	Travel (study tours)		18,950.00	16,025.00	34,975.00	
				74500	Miscellaneous Expenses (Workshops)	8,900.00	8,900.00	8,900.00	26,700.00	
					Sub-total	36,600.00	27,850.00	24,925.00	89,375.00	

			GOM	71600	Travel (study tours)	227,630.00	227,630.00	227,630.00	682,890.00
					Sub-total	227,630.00	227,630.00	227,630.00	682,890.00
2	Enhanced scientific, socio-economic and institutional capacities for risk assessment	Ministry of Natural Resources and Environment	GEF	71200	International Consultants	30,505.00			30,505.00
				74500	Miscellaneous Expenses (Workshops)	25,000.00	25,000.00	25,000.00	75,000.00
					Sub-total	55,505.00	25,000.00	25,000.00	105,505.00
			GOM	71300	Local Consultants	41,390.00	41,390.00	41,390.00	124,170.00
				72200	Equipment	822,281.60	397,878.40	79,576.00	1,299,736.00
					Sub-total	863,671.60	439,268.40	120,966.00	1,423,906.00
3	Increased capacity for developing and implementing a risk management programme	Ministry of Natural Resources and Environment	GEF	71300	Local Consultants	50,000.00	20,000.00	30,000.00	100,000.00
				74500	Miscellaneous Expenses (Workshops)	34,500.00	25,928.80	44,500.00	108,500.00
					Sub-total	84,500.00	49,500.00	74,500.00	208,500.00
			GOM	71300	Local Consultants	362,550.00	362,550.00	362,550.00	1,087,650.00
					Sub-total	362,550.00	362,550.00	362,550.00	1,087,650.00
4	Developed capacity for long term operation and maintenance	Ministry of Natural Resources and Environment	GEF	71200	International Consultants			20,000.00	20,000.00
				71300	Local Consultants	8,000.00	16,000.00	11,700.00	35,700.00
				72200	Equipment	50,000.00			50,000.00

				74500	Miscellaneous Expenses (Workshops)	20,000.00	20,000.00	20,000.00	60,000.00
					Sub-total	78,000.00	36,000.00	51,700.00	165,700.00
			GOM	71300	Local Consultants	56,000.00	56,000.00	56,000.00	168,000.00
					Sub-total	56,000.00	56,000.00	56,000.00	168,000.00
5	Improved information sharing and coordination between institutions and agencies	Ministry of Natural Resources and Environment	GEF	71200	International Consultants	11,700.00	9,700.00	9,700.00	31,100.00
				72200	Equipment	10,000.00			10,000.00
				74500	Miscellaneous Expenses (Workshops)	5,500.00	3,500.00	5,500.00	14,500.00
					Sub-total	27,200.00	13,200.00	15,200.00	55,600.00
			GOM	71300	Local Consultants	24,000.00	24,000.00	24,000.00	72,000.00
					Sub-total	24,000.00	24,000.00	24,000.00	72,000.00
6	Increased public awareness on biotechnology and biosafety	Ministry of Natural Resources and Environment	GEF	71300	Local Consultants	10,000.00	10,000.00	7,000.00	27,000.00
				74500	Miscellaneous Expenses (Workshops)	16,700.00	1,000.00	1,000.00	18,700.00
				74200	Audio Visual & Print Prod. Cost	7,000.00	7,000.00		14,000.00
					Sub-total	33,700.00	18,000.00	8,000.00	59,700.00
			GOM	71300	Local Consultants	68,419.00	68,419.00	68,419.00	205,257.00
				74500	Miscellaneous Expenses (Workshops)	213,824.00	213,824.00	213,824.00	641,472.00

					Sub-total					
						282,243.00	282,243.00	282,243.00	846,729.00	
				TOTAL GEF CONTRIBUTION						911,380
				TOTAL GOM CONTRIBUTION						4,303,175.00
				GRAND TOTAL						5,214,555.00

ANNEX 4

TOR for National Steering Committee

The National Project Steering Committee (NSC) will monitor the conduct of the project and provide guidance and direction to the project team at the strategic level. NSC's responsibilities include: -

- Reviewing progress of project;
- Approving major project deliverables;
- Reviewing issues raised and agreeing to action plans for their resolutions;
- Monitoring the continued applicability of project benefits; and
- Approving Change Requests (e.g. scope changes, schedule alterations, personnel).

The Committee will comprise the main stakeholders, including the following:

- Conservation and Environmental Management Division, Ministry of Natural Resources and Environment (NRE),
- Genetic Modification Advisory Committee (GMAC) and NBB;
- Economic Planning Unit (EPU);
- Ministry of Agriculture, and Agro-based Industries;
- Ministry of Science, Technology and Innovation;
- Ministry of Health, Department of Public Health;
- Ministry of Plantation Industries and Commodities;
- Ministry of International Trade and Industry (MITI);
- Ministry of Domestic Trade and Consumer Affairs;
- Ministry of Information;
- Ministry of Finance, Department of Royal Customs and Excise;
- Ministry of Higher Education;
- Private corporations (biotechnology companies, plantation companies and other companies dealing or trading in biotechnology products);
- NGOs for biotechnology, environment and consumers (Third World Network, World Wide Fund for Nature Malaysia, the Malayan Nature Society, Federation of Malaysian Consumers Associations);
- UNDP

ANNEX 5

TOR for National Project Director

The Director General of the National Biosafety Board (NBB) of the Ministry of Natural Resources and Environment (NRE) will be the National Project Director. This person will be mainly responsible for coordination of project activities among the different partners of the project. These will include various government agencies, NGOs, UNDP and consultants.

The responsibilities of National Project Director include:

- Leading and managing the National Project Team;
- Ensuring that all project objectives and outputs are satisfied;
- Managing the project budget in accordance with GoM/UNDP guidelines;
- Assisting NSC in the selection of members for the Project Team and consultants;
- Reviewing annual work plan and budget;
- Ensuring that all activities are completed according to schedule;
- Ensuring that the GEF project document is satisfactorily completed and submitted on time

ANNEX 6

TOR for National Project Coordinator

Duties

- Act as Executive Secretary to the PCC and the NSC;
- Prepare an annual work plan on the basis of the project document;
Under the direction of NPD and the NSC, and in close consultation with other stakeholders of the project;
- Coordinate and monitor the implementation of the project as set out in the project document and recommending any such modifications/revisions as may be necessary to the NSC through the NPD;
- Manage and coordinate with relevant governmental bodies and participating institutions or agencies involved in the project execution;
- Review consultants' reports (ensuring quality of the reports), project budget revisions and all other administrative arrangements required as per NRE and UNDP;
- Certify services rendered by contractors and the consultants for purposes of payment, where provided for;
- Prepare and submit quarterly reports to the PCC on progress and problems faced in the project and any other reports as may be required, through the NPD to the NSC;
- Chair monthly progress meetings;
- Implement the project in accordance with the project document milestones; and
- Undertake any other duties as may be assigned by the NPD and the NSC.

ANNEX 7

TOR for Project Assistant

Duties

The Project Assistant shall report directly to the Project Coordinator and shall be responsible for:-

- Providing administrative and logistic support to the project team;
- Managing schedules and project implementation within specified project constraints;
- Undertaking secretariat services to specific project activities;
- Providing limited backup support to the team;
- Providing financial and limited backup support to the project team;
- Executing financial and budgetary tasks and related activities;

ANNEX 8

TOR for Project Management Unit

The Project Management Unit will be established to provide accountability and in the execution of the project. The Project Management Unit will be located at the local implementing agency and will comprise:

- National Project Director - Chairperson
- National Project Coordinator - Secretary
- UNDP Representative
- Consultants when required

The PMU shall:

- Advise the NSC on all functions of procurement of good and services
- Ensure that all expenditures and financial procedures pertaining to purchases, procurement, award of contracts are on a completion basis and in compliance with GoM/UNDP guidelines;
- Review annual work plan and budget for timely submission to the NSC;
- Oversee project activities to ensure that they are consistent with those outlined in the project document;
- Review progress of work and revise work plan, if necessary;
- Submit regular progress reports, including any revisions of work plan and budget to NSC and UNDP;
- Monitor and coordinate all components of the project in accordance with the work plan.

ANNEX 9

NRE/UNDP/GEF INCEPTION WORKSHOP SUMMARY REPORT ON SUPPORT TO CAPACITY BUILDING ACTIVITIES ON IMPLEMENTING THE CARTAGENA PROTOCOL ON BIOSAFETY

1. OPENING

The Inception workshop is jointly organized by the Ministry of Natural Resources and Environment (NRE) and United Nations Development Programme (UNDP), Malaysia. It had a good attendance with a mixture of stakeholders from the various sectors (government agencies, non-government organizations, non-profit organization, private sector, academia, research institutes, UN Bodies, industry and members of the media).

The objective of this workshop was to serve as an introductory session on the NRE/UNDP/GEF Biosafety Project to all national stakeholders and to provide them with an opportunity to comment on and recommend activities for the project and identify respective roles and involvement.

The workshop was officially opened by Hon. Dato' S Sothinathan, Deputy Minister of NRE. The workshop started with welcome notes from Dr Lian Kok Fei (Under Secretary, Ministry of NRE) and Mr Hari Ramalu Ragavan (Programme Manager, UNDP Biosafety Programme Manager). A press conference was held to raise awareness and publicize the objectives and activities of the projects.

2. PLENARY SESSION

The panel consisted of Mr K. Nagulendran from NRE, Dr Vilasini Pillai who is the National Project Coordinator, Dr Low Fee Chon from UNEP Bangkok and Mr Hari Ramalu Ragavan from UNDP Malaysia. The session was chaired by Mr Letchumanan Ramatha, Deputy Under Secretary, NRE. Members of the panel gave their presentation and the Q&A session was held after all the presentations.

Cartagena Protocol on Biosafety and the Malaysian Biosafety Framework

K. Nagulendran, NRE

Mr K. Nagulendran from the Ministry of NRE gave a comprehensive overview of the Cartagena Protocol and Biosafety activities in Malaysia and the important need for capacity building for the implementation of the new Biosafety Law. The foundation of the Cartagena Protocol is to ensure the flow/movement of any living modified organism but at the same time guarding the safety of biodiversity. Among the concerns raised about Genetically Modified Organism (GMOs) are its potential for transfer material-cross pollination, contamination into wild species, implications on Intellectual Property Rights, socioeconomic impact that may infringe on ethical and religious beliefs. Therefore, there is a need for Biosafety for a country to start governing its biotechnology advancement. The Malaysian Biosafety Framework covers administrative, legal, policy, monitoring, support services, scientific advice, enforcement, decision-making bodies, public participation and policy. The Bill is very facilitative to research and is meant to safeguard our GMOs. Passing of the Biosafety Law will also help boost the confidence of investors and gives a fair balance.

Introduction to Malaysian Biosafety UNDP-GEF Project

Dr Vilasini Pillai, National Project Coordinator

The Malaysian Biosafety Project was explained in greater detail by Dr Vilasini Pillai, the National Project Coordinator. Dr Vila highlighted the objectives and project components and its related expected outputs and activities. Dr Vila mentioned that one of the objectives of the workshop was to obtain help in prioritizing these activities and revising or adding more activities (should it be necessary).

GEF Capacity Development Initiative for Multilateral Environmental Agreements

Mr Hari Ramalu Ragavan, UNDP

Mr Hari Ramalu Ragavan said that this is not a UNDP project but a project of the Government of Malaysia. UNDP's role is to support financially and technically. This is the third enabling project that GEF is working currently in Malaysia. He advised everyone to take a good look at the project document and ensure that the output and activity of the project is currently relevant and will still be for years to come. Everyone was encouraged to give their input and output on the project so that it will continue to be relevant. However, he cautioned that the objective and outcome of the project cannot be

changed. It is only possible to change the output and activity level (which is important because this is what will contribute the most). In addition to that, he also explained the mechanism of overall implementation, monitoring, reporting and reviewing structure for this project.

UNEP Technical Assistance for Biosafety Capacity Building

Dr Low Fee Chon, UNEP, Bangkok

The Plenary session ended with the presentation of Dr Low Fee Chon from UNEP Bangkok who shared her rich experience in UNEP Technical Assistance for Biosafety Capacity Building. Dr Low quoted many examples from her previous projects and also helped to highlight expected challenges, expected outcomes as well as precautions and issues for consideration when implementing this project. As national priorities vary from country to country and region to region, Malaysia must decide what its priorities are and ensure that the priorities are addressed in the project. The project must also be fully driven and managed by the country as UNEP's role is solely to advise the country. Hence the national project team must be very active and efficient. Dr Low mentioned that it is important for a country involved in the project to include as many stakeholders as possible. The reason is because Dr Low finds that the more stakeholders that are consulted, the greater the country's ownership and interest to follow through the project leading to a greater chance of success. As for technical support services, Dr. Low encourages a country to look for experts firstly within their own country before sourcing out for regional experts.

3. QUESTION & ANSWER SESSION ON THE PLENARY

Some issues that were brought up during the question and answer session are listed below:

a) Public awareness

- Creating public awareness on biosafety is very important
- Present awareness is very low and we need to think of how to incorporate awareness into higher level institutes
- Accuracy of information that goes out to the public is important
- Information conveyed about biotechnology should be a balanced view looking into both pros and cons of the technology
- There is a need to develop a communications strategy to deal with different stakeholders as biosafety is very diverse
- University Malaya has already introduced a postgraduate diploma in Biosafety and other universities are bound to follow
- NRE will work closely with many NGOs in educating the public and putting out the right information.
- Media was urged to make responsible reporting and check the information so that the science itself is accurate to avoid misinformation.
- There has been a lot of focus on biotechnology but not on biodiversity However, that does not mean that biodiversity is overlooked.

b) Genetically Modified Organism (GMOs)

- Classification of GMOs is up to the individual countries to do so according to their law and regulations and defined classified risk levels. NRE will be looking into this.
- There are already GMOs produced through research. Therefore, biosafety should not be seen as hampering research and development, but instead complementing the work of scientists.
- Mechanisms will be in place to put in the applications with standard rules, procedures and application forms.
- Scientists, institutions, etc. who intend to conduct field releases are urged to come forward to notify and obtain approval before release is made. However, for laboratory containment, notification is sufficient as long as it adheres to the law and regulation.

- If a GMO that is proven to be unsafe is released by accident, it is up to the country to regulate an Emergency Response Plan (ERP) to recover from national disaster, food shortage etc.

c) Public Participation

- Public participation is paramount importance in this project.
- Assurance was given by NRE that the public input will be taken into consideration and that public participation is definitely encouraged.
- If the concerns are sensible, then NRE can devise the provision.

4. RESULTS FRAMEWORK DISCUSSION

The participants were divided into groups according to their respective sectors and given the opportunity to scrutinize the project's Results Framework (Appendix A) and give their inputs. Each group shared their suggestions and comments to the whole workshop after much discussion among themselves. The summary of decision on the revisions to the Results Framework is provided in the main report.

4.1 GROUP 1- GOVERNMENT

Chairperson: Bhupindar Singh (Jabatan Peguam Negara)

Rapporteur: Joanne Bulan Pakar (MoA)

Group Members:

No.	Members Name	Organization
1	Azlina Aziz	UPEN Pahang
2	Bhupinder Singh	Jabatan Peguam Negara
3	Dr. Devan Kurup	Caw. Survelan, Bhg Kawalan Penyakit, MoH
4	Joanne Bulan Pakar	MoA
5	Low Lai Yoong	Kem. Perusahaan Perladangan & Komoditi
6	Mohd Shukri Azam	UPEN Terangganu
7	Mohd Zamzuri Khalid	Jab. Hal Ehwal Pelbagai Hala, Kem. Luar Negeri
8	Nur Azarina Abu Bakar	Jabatan Pertanian
9	Rajamany T. Ramasamy	MoA
10	Runi Sylvester Pungga	UPEN Sarawak
11	Zulhusni Mohamad Rashid	UPEN Kedah
12	Shamsinar Abdul Talib	MoH
13	Zulkafli A.Rashid	Dept. of Fisheries
14	Muhammad Razali	KPDN HEP

SECTION	COMMENTS/ SUGGESTIONS
1.1.1	Cite some application from other countries as samples. Have the secretariat to prepare some working drafts.
1.2.1	These three need more identification, and risk management is not appropriate for enforcement officers. Workshop should include basic knowledge for inspection - <i>investigation skills/ procedures</i> - <i>documents/ samples checking and inspection</i>
1.3.1	Add on that - workshop should include the handling import and contained use of LMOs
2 and 3	Group agrees on everything
4.2.1	Commented that purchase of hardware (e.g. Lab equipments) is also important
4.3.1	Workshop for food and safety is not necessary for these officers as it is already done by researchers and scientists (refer to No 2) - <i>Food and feed safety</i>
5	Group agrees on everything
6.1.1	Training should be for the NBB, not for the IT specialists. NBB should know the biosafety issues and identify biosafety information
6.3.1	Add on 'to do road shows' to create stakeholder awareness

4.2 GROUP 2- GOVERNMENT

Chairperson: Ms Atikah Abdul Kadir Jailani (DOA)

Rapporteur: Ho Haw Leng (DOA)

Group Members:

No.	Members Name	Organization
1	Arizal Arshad	Jabatan Pertanian
2	Atikah Abdul Kadir Jailani	Jabatan Pertanian
3	Ernie Muneerah	Jabatan Perkhidmatan Haiwan, MoA
4	Ismail Ishak	Jabatan Perikanan Malaysia
5	Nor Azaruddin Husni	IKIM
6	Rohanah Mohd Yasin	Pusat Bioteknologi
7	Dr. Maizura Ithnin	MPOB
8	Nor Mayati Che Husin	Lembaga Getah Malaysia
9	Wong Wan Cheng	Jabatan Pertanian
10	Dr. Cheong Weng Chung	MOSTI
11	Arman Mohamad Shah	UPEN Johor
12	Khairun Hisam	MARDI
13	Che Hassan Pahmi	JAKIM
14	Rosmidzatul Azila	IKIM
15	Ho Haw Leng	Jabatan Pertanian

SECTION	COMMENTS/ SUGGESTIONS
1	Overall input - propose that there should be a timeline in place.
1.1	There should be some Standard Operations Procedures (SOP), inspection, detection procedure organized for these workshops
1.1.1	<i>Detection and release of LMO</i>
1.2.1	Propose to include additional workshop on indicative activities such as LMO inspection, sampling and detention
1.4	DELETE
2.1	There should be additional indicative activities in workshop for impact studies on ethical issues with regards to animal GMOs
3	Group agrees on everything
4.1	Propose bracket for MoA and East Malaysia to be deleted.
4.2	Propose to cancel the visits and use money use for purchasing software, hardware and maintenance Include upgrading and purchasing manuals for laboratories in organizations dealing with GMOs such as MOH and Jabatan Kimia. <i>DOA – purchasing</i>
4.4	DELETE
5.1	Propose some other agencies, like what authorities should be involved in this area. Add – port authority
6.1.1	Website that has been developed, propose that the website should be some sort of interactive site for public and authority to interact, people who are involved in LMOs and GMOs.
6.3.1	Agree with Group 6 that curriculum for school and higher institute should be involved in biosafety. Add on indicative activity.

4.3 GROUP 3- RESEARCH INSTITUTES

Chairperson: Dr Ahmad Parveez (MPOB)

Rapporteur: M.S. Paramasvaran (IMR)

Group Members:

No.	Members Name	Organization
1	Dr. Ahmad Parveez	MPOB
2	Dr. Azizah Mohd Radzi	IMR
3	Dr. Habibuddin Hashim	Pusat Bioteknologi
4	Dr. Noor Zaleha	Jabatan Kimia Malaysia
5	Dr. Normaznah Yahaya	IMR
6	Dr. Rajinder Singh	MPOB
7	Dr. Siti Arija Mad Arif	Lembaga Getah Malaysia
8	M.S Paramasvaran	IMR
9	Rogayah Sekeli	Pusat Bioteknologi

SECTION	COMMENTS/ SUGGESTIONS
1	We should provide guidelines for people working with GMOs in confined GMO experiments/trials and import. At this point of time, just notify the group, there must be good guidelines and SOP.
1.4	Include online application
1.2.4	Need dedicated and competent biosafety officers.
1.3	20 members not enough, suggest 50 people including GMAC members and IBC members.
1.4	Invite experts from overseas to brief on their areas of expertise
2.1.1	Risk assessment should cover environment impact, socioeconomic and ethical impact
2.3	Minimum 3 technical workshops
2.4	The group also felt that the workshop should include more ministries such MOE, women and health, ministry of information, JAKIM and perhaps the interfaith council.
3.1.1	A well detailed emergency response plan must be elaborated followed up with a damage control plan for residue.
6	Appoint Biotechnology Biosafety Communicator at NBB (PR Office)
6.2	Training to include <ul style="list-style-type: none"> ➤ Ministry of Education ➤ Ministry of Women & Health ➤ Ministry of Information ➤ JAKIM/ International council ➤ MITI
	Biosecurity has not been discussed. Safety is integral part, and we should think of biological safety. There is a need for a resource centre which public to access and people to consult and get help from.

4.4 GROUP 4- NON-GOVERNMENT ORGANISATIONS

Chairperson: Mohd Nizam Mahshar (SAM)

Rapporteur: Preetha Sankar (WWF)

Group Members:

No.	Members Name	Organization
1	Benjamin Loh	MENGO Support Unit
2	Chee Yoke Heong	Third World Network
3	Gabriel Chong	Wetland International
4	Lee Shin Shin	Wetland International
5	Lim Li Ching	Third World Network
6	Mahaletchumy Arujanan	MABIC
7	Mohd Nizam Mahshar	Sahabat Alam Malaysia (SAM)
8	Mohd Shah Rizan Sazali	Persatuan Pengguna Pulau Pinang
9	Piarapakaran Subramaniam	FOMCA
10	Wan Azilina Wan Ahmad	Sahabat Alam Malaysia (SAM)
11	Dr. Latifah Amin	Centre for General Studies, UKM
12	Preetha Sankar	WWF Malaysia

SECTION	COMMENTS/ SUGGESTIONS
	Strengthen legal framework. There are regulations to be prescribed later, should have consultative workshops. Issue of labeling, liability and redress, further details
1.1	Broaden stakeholder base, include media, farmers' organizations, lawmakers/legal fraternity, religions groups Indicative activities -exemption from AIA NOT a priority -consultation on the application process rather than merely on the application form
1.1.1	Talking very much about application form, where applicants submit. Is identifying products for exemption at this stage necessary? What needs to be in place is process and mechanisms, focus should be on consultative application process
1.2	Some of the things listed as training as basic, unapproved GMOs, what do you do? What is there is unintentional transboundary movement, emergency procedures/measures could be added in.
1.4	Important to learn the lessons from countries with robust framework such as EU, Austria or Japan and assimilate into our process and countries that have experience where there is unintentional release, purgatory responses, when that happens. Members of GMAC, cross project study tours, lessons learnt should be made public. Activities to add: learn from Emergency Response Plan (overseas)

1.5	<p>Activity -to make lessons learnt public</p> <p>Add on intended output: Strengthening -Legal mechanisms/frameworks, identify gaps, production of guidelines (procedural or otherwise) -Could be done consultatively through series of workshops with stakeholders -Socio-economic component and how these factors are integrated in the Act</p>
2	Good to have series of workshop that has been identified, have clear socio economic issues.
2.3	Looking at relations to different technical workshop, preparation of dossiers for field release - Not clear what this meant. How to effectively conduct risk assessment coming from applicant.
3	Group agrees on everything.
4	One of the things is long-term capacity. Some proposal into other activities, curriculum etc is valuable
4.1	General laboratories identify mechanism of credibility of labs and results that come from them (which may include certification/accreditation of the operations). Felt that it would be important that a mechanism be identified. If there is unapproved GMOs, how do we go about it, public can bring issue to authorities and verified. Development of a mechanism that would allow members of the public to independently verify a particular GMO (at these labs)
5.1	<p>Should not be limited to listed agencies. Information should not be just between agencies but also to public. Not limit to 60-80 officers. Include all stakeholders. Have policy in biosafety bioregulation, transparency in terms of public focus on the issue.</p> <p>Indicative activities- Add in: information sharing for general public – develop mechanism and policy in biosafety regulation on accessibility and transparency</p>
6	<p>Confidential business information. Website that function as portal of general information and should have applications with CBJ. Can be discussed to what format, how much it needs to be put on, available to public. Should be under public awareness for public feedback and comment. Awareness material developed with NGOs that have experience. Awareness should be science based and factual. Higher education that focuses on biosafety, and biotech programme, biosafety should become common.</p> <p>Activities:</p> <ul style="list-style-type: none"> ▪ Mechanism for effective public complaints, feedbacks and comments on the application ▪ Develop awareness materials (science based and facts) and awareness programmes with NGOs ▪ To have biosafety component in higher education under Biotechnology course
6.3.1	Producing education kits, focus not on technology promotion, but biosafety. Target groups to be identified and quantified, need to focus on regulatory

	mechanisms. Issue of language, reach a wide public and produce in different languages. Evaluation of the effectiveness of the awareness programme. Set up review committee to review the awareness material.
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4.5 GROUP 5- PRIVATE SECTOR

Chairperson: Suryna Ali (International Consultant)

Rapporteur: Ahmad Farid b. Ahmad (UPEN Selangor)

Group Members:

No.	Members Name	Organization
1	Dr. Woon Weng Chuen	UNDP – GEF BiO, FRIM
2	Maznor Maznan	UNDP - GEF Marine Park
3	Chua Hooi Dean	UNDP - GEF Marine Park
4	Siti Habsah Roowi	Felda Technology Centre
5	Suryna Ali	International Consultant on Biodiversity
6	Tony Ooi	BiOTech Corporation
7	Ung Eng Huan	Global Satria Sdn Bhd
8	Prof Madya Dr. Noraini Mohamad	MoHE
9	Ahmad Farid	UPEN Selangor
10	Dr. Normala Halimoon	UNISEL
11	Mohd Rofandi Sulong	UNISEL
12	Suraiza Abdullah	FMM

SECTION	COMMENTS/ SUGGESTIONS
5.1	<p>Before improving information sharing, we have to identify stakeholders. Private sector (pharmaceutical, Bionexus, Fed Malaysian Manufacturers, Chambers of Commerce NGOs (TWN, SAM, MSN, TRAFFIC, WWF, MENGO) and government (Ministry of Higher Education, State government as well as their entities, enforcement).</p> <p>a) Private sectors</p> <ul style="list-style-type: none"> ➤ Communication ➤ Food/aquaculture ➤ Pharmaceutical ➤ Bionexus ➤ Federation of Malaysian Manufacturers ➤ Business council sustainable development Malaysia ➤ Private equity fund ➤ Chambers of commerce <p>b) NGOs</p> <ul style="list-style-type: none"> ➤ Third World Network ➤ WWF ➤ TRAFFIC ➤ MNS ➤ SAM ➤ CETDEM ➤ MENGO <p>c) MOHE</p>

	<p>d) State government and entities</p> <p>e) Jadual 3 (Biosafety Act) – Enforcement Officers Communication framework needs to be established for target decision makers. Secretary General of ministries, make is simple and clear, scientific terms to simple layman terms, identify liaison units, in state and ministries, coverage from medias, e.g. of launching of <i>buku hijau</i>, have selection criteria of Training of Trainers.</p> <p>Have a Communication Framework</p> <ul style="list-style-type: none"> ➤ Target decision makers ➤ have it simple and clear ➤ Liaison Unit ➤ Coverage from media ➤ Selection criteria for TOT
<p>5.2</p>	<p>Database</p> <ul style="list-style-type: none"> -uniform format at international level or country – unique -protect confidential MFO -public info access -location of database -personnel of database should be permanent -synchronize database system compatible system -IT personnel under whose jurisdiction? AG's, advisory committee board -developments of software
<p>5.3</p>	<p>Presentation has to be brief and simple.</p> <p>Database - clarify that we have to first establish database. Information should be well protected, however, public has to have access. Good application of the database is if it can be used to check if the product is approved by the government</p> <p>Personnel looking for database should be synchronized, within the state, ministry, IT personnel under whole jurisdiction, Advisory committee, Nation Advisory Board.</p> <p>Key person to administer the database must be identified and personal responsible for the database should be permanent.</p>
<p>5.4</p>	<p>Workshop should be organized second year of project and discuss cost benefit analysis.</p>

4.6 GROUP 6- ACADEMIA

Chairperson: Dr Rofina Yasmin Othman (UM)

Rapporteur: Dr Alan Ong Han Kiat (UTAR)

Group Members:

No.	Members Name	Organization
1	Prof Dr. Shaik Mohd Noor	Pejabat Pendaftar, UPM
2	Prof Madya Dr. Norihan	Fakulti Bioteknologi & Sains Biomolekul UPM
3	Prof Madya Dr Abdul Rahman	Institut Biosains, UPM
4	Dr. Alan Ong Han Kiat	UNITAR
5	Loke Chui Fung	TAR College
6	Dr. Jennifer Ann Harikrishna	UM
7	Prof Helen Nair	AMIST
8	Rozila Alias	UNISEL
9	Prof Madya Dr Noor Hana	Faculty of Applied Science, UiTM
10	Prof Madya Dr Noor Hasima	UM
11	Tengku Haziyaamin	UIA
12	Prof Dr Rofina Yasmin	UM

SECTION	COMMENTS/ SUGGESTIONS
	<ul style="list-style-type: none"> ▪ The group decided on certain prioritizing as they felt that the Log frame did not prioritize certain activities. The group decided to put as a pre-requisite the following before proceeding to all the activities <ol style="list-style-type: none"> 1. First meeting should be regulatory requirement before going in the different requirement. 2. Identify required implementing instruments, assuming that instruments are already designed. 3. Harmonization of the existing law, priority at the beginning of the programme 4. No 5.1.1 should be part of harmonization collaborating agencies on the need of harmonization. ▪ Before starting the programme, this should be done. Then the workshop listed here are fine. ▪ Consultancy workshops are ok as long as instrumentations are intact. ▪ Log frame should be divided into roles of stakeholders i.e. what is the role of NBB? GMAC? Stakeholders? The roles are currently all mixed up.
1.1	Addition of other stakeholders including relevant industry, retailers who handle GMO, scientific organizations like Genetic Society of Malaysia, farmers' association, relevant industries, media, public figures, social scientific organization, NGO etc.
1.1.1	<p>Before calling stakeholders, it is useful to check knowledge level of stakeholders.</p> <p>Another workshop on labeling issues and scope of contained use (manufacturing and production)</p> <p>Workshop logistic?</p> <ol style="list-style-type: none"> 1. Pre-requisite <ul style="list-style-type: none"> -Review of the regulatory requirements of the primary law -Identify required implementing instruments

	-Harmonization with existing laws i.e. Quarantines, Food, Variety -Fast track procedures
1.5.1	Cross project learning, study tour. Attended by policy makers and law makers. Stress Institute of Biosafety Committee (IBC) rep, as they are the frontline of doing enforcement.
2	Group agrees on everything
3	Include workshop on establishment of IBC, how it is linked to NBB, standardization of forms and review procedure at IBC level
3.1	Should include 'aquatic plants'
3.1.1	Rephrase 'Post release land use' to 'Post release environment impact'
3.2	Why fish is separated quoted from animals? i.e. ...fish and animals....
3.4	Bio-pharming has been singled out. Animals are also used for biopharming – should read 'plants and animals used for biopharming'
4.1	Training of scientists, MoA and include research institutes and universities who want to set up laboratories and would have some accredited labs.
5.1	Should be priority activity including 5.1.1. Workshop for collaborating government organizations.
5.2	Should be mentioned that should be linked to International Clearing House databases
5.4.1	Workshop to share information – include information on application and decision, confidentiality and information and health impact studies
6.2	Add scientists and other professionals
6.3	Increased public awareness - agree roadshows are important. Academic on curriculum development, secondary and tertiary and continuing education for professionals, inbuilt into training programmes in schools.

5. WRAP-UP AND CONCLUSION

Mr Nagu assured all participants that the inputs given have been recorded and that it will be put into the Results Framework and passed on to the National Steering Committee (NSC) for approval. Mr Nagu expressed his appreciation for active participation and contribution and reminded all participants that this is a Malaysian project and the stakeholders will be contacted soon as the next stage would be to come up with regulations. Mr Nagu closed the workshop by giving special thanks to Mr Hari from UNDP and Dr Loh from UNEP, Bangkok.

Rapporteurs: *Anita Anthonysamy, Azareena Y. and David Lee*

APPENDIX A

NRE/UNDP/GEF PROJECT FRAMEWORK OF CAPACITY BUILDING ACTIVITIES ON IMPLEMENTING THE CARTAGENA PROTOCOL ON BIOSAFETY AND NATIONAL BIOSAFETY FRAMEWORK

INTENDED OUTPUT	OUTPUT TARGETS	INDICATIVE ACTIVITIES
<p>1 Effectively implemented legal framework on biosafety</p>	<p>1.1 Consultative Workshops on the administration and implementation of the Malaysian Biosafety Act for all stakeholders organized. About 150 participants from the public and private biotechnology sectors, academia, researchers, regulators, policy makers and NGOs invited.</p> <p>1.2 A “training the trainers” workshop for 50 enforcement officers from different ministries and the Customs Board to regulate import of LMOs at points of entry into the country organized.</p> <p>1.3 Workshop on handling applications for 20 including GMAC members and other regulators organized</p> <p>1.4 Study tours of GMAC members, (in groups of 2-3) to various foreign countries which have an established biosafety institutional and administrative structure undertaken.</p>	<p>1.1.1 Organize a series of consultative workshops to:</p> <ul style="list-style-type: none"> • Review proposed application forms for release of LMOs • Identify products to be exempted from AIA and approval regimes • Review the utility of the “User Guide to making an application” for a user-friendly application process. <p>1.2.1 Organise a special workshop for enforcement officers to acquire basic knowledge in:</p> <ul style="list-style-type: none"> • LMO identification • AIA procedures • Risk management <p>1.3.1 Organize “Hands-on” workshop on handling requests and applications for release of LMOs, using real dossiers and administered under the proposed Biosafety Act.</p> <p>1.4.1 GMAC members to visit similar biosafety regulatory bodies to:</p> <ul style="list-style-type: none"> • Learn the implementation of their biosafety framework • Be updated on best practices in biosafety • Share experience with counterparts abroad

INTENDED OUTPUT	OUTPUT TRARGETS	INDICATIVE ACTIVITIES
	<p>1.5 Cross project learning study tours and international meetings on biosafety related issues attended by policy makers, lawmakers and regulators.</p>	<p>1.5.1 Key policy makers, lawmakers and regulators to attend international meetings and study tours on biosafety to:</p> <ul style="list-style-type: none"> • Be familiar with international best practices • Cross-project learning with other UNDP and UNEP capacity building projects by NBB staff.
<p>2 Enhanced scientific, socio-economic and institutional capacities for risk assessment</p>	<p>2.1 Technical training workshops including quantitative detection of GMO and products for 60-80 scientists, regulators and scientists & technicians from the GMO Detection Laboratories organized</p> <p>2.2 Workshop on long-term monitoring for 60 scientists, sociologists, environmentalists, regulators, private industry and NGOs to evaluate the impact of the release of LMOs into the environment organized</p> <p>2.3 Technical workshop on preparation of dossiers for field release of LMOs for 60 scientists and academicians from R&D institutions and universities organized.</p> <p>2.4 Technical workshop on food/feed safety assessment of GMF for 60</p>	<p>2.1.1 Organize a series of workshops for:</p> <ul style="list-style-type: none"> • GMO & products detection • Quantitative measurement for the presence of GMO & products in food, feed and others. • Food & feed safety assessment • Risk assessment • Risk management • Up-grading skills and techniques <p>2.2.1 Organize a workshop for:</p> <ul style="list-style-type: none"> • Monitoring, reviewing and reporting of effectiveness of risk management • Assessment methods • Long term impact analysis • Cost benefit analysis <p>2.3.1 Organize a workshop on preparation of dossiers for field release application:</p> <ul style="list-style-type: none"> • Biology of parental organism • Intended use • Receiving environment <p>2.4.1 <i>Organize a workshop on:</i></p> <ul style="list-style-type: none"> • Food/feed safety assessment methods

INTENDED OUTPUT	OUTPUT TRARGETS	INDICATIVE ACTIVITIES
	food scientists, Health officials, regulators and academicians from R&D institutions and universities organized.	<ul style="list-style-type: none"> • Validation of safety data • Long term impact analysis.
3 Increased capacity for developing and implementing a risk management programme	3.1 Technical training workshops for between 80-120 researchers, academicians and regulators on risk management of GM crop plants (annuals) organized. 3.2 Technical training workshops for 80-120 researchers, academicians and regulators on risk management of GM microbes, fish and animals organized. 3.3 Technical training workshops for 60-80 researchers, academicians and regulators on risk management of GM trees (perennials) organized. 3.4 Technical training workshops for 60-80 researchers, academicians and regulators on risk management of GM plants used for bio-pharming organized	3.1.1 Organize a series of workshops for: <ul style="list-style-type: none"> • Risk identification • Risk evaluation • Risk mitigation • Emergency response plan • Post release Monitoring • Post release land use 3.2.1 Organize a series of workshops for: <ul style="list-style-type: none"> • Risk identification • Risk evaluation • Risk mitigation • Emergency response plan • Post release Monitoring 3.3.1 Organize a series of workshops for: <ul style="list-style-type: none"> • Risk identification • Risk evaluation • Risk mitigation • Emergency response plan • Post release Monitoring 3.4.1 Organize a series of workshops for: <ul style="list-style-type: none"> • Risk identification • Risk evaluation • Risk mitigation • Emergency response plan • Post release Monitoring

INTENDED OUTPUT	OUTPUT TARGETS	INDICATIVE ACTIVITIES
<p>4 Developed capacity for long-term operation and maintenance</p>	<p>4.1 40-50 scientists and technicians to operate the GMO Laboratory recruited and trained. -Chemistry Dept -MOH -MOA (proposed) - East Malaysia (proposed)</p> <p>4.2 Visit by 2 senior scientists to centers of excellence for GMO detection outside the country to learn about the required hard- and software viz. their utility, robustness and cost effectiveness, prior to their purchase undertaken.</p> <p>4.3 Workshop on long-term enforcement of food and feed safety for 60 enforcement officers, food scientists, food manufacturers and NGOs organized.</p> <p>4.4 Technical visit by 2 NBB officials to meet counterparts in other National Competent Authorities abroad carried out.</p> <p>4.5 Workshop for 50 Legal Advisors from relevant Ministries and Principle Investigators from research institutes and universities on biosafety, IPR, international obligations and other the legal matters organized.</p>	<p>4.1.1 “Hands-on” training for scientists and staff in:</p> <ul style="list-style-type: none"> • Basic molecular biology techniques • Access and utilization of molecular biology software, databases, etc. for primer design • GMO handling & preparation for analysis • Records and reporting procedures <p>4.2.1 Purchase software for the GMO Labs.</p> <p>4.3.1 Organize a workshop on:</p> <ul style="list-style-type: none"> • Monitoring procedures for food and feed safety • Sampling for food and feed safety assessment, • Recording and reporting procedures <p>4.4.1 Technical visit by 2 NBB officials to meet counterparts in other National Competent Authorities abroad to share experience on the implementation of the technical aspects of the Malaysian Biosafety Act.</p> <p>4.5.1 Training workshop to discuss:</p> <ul style="list-style-type: none"> • Biosafety legal issues • IPR, MTA and other legal instruments for R&D and commercialization of biotechnology products.

INTENDED OUTPUT	OUTPUT TARGETS	INDICATIVE ACTIVITIES
<p>5 Improved information sharing and coordination between institutions and agencies</p>	<p>5.1 Workshop for 60-80 senior officers from government agencies, enforcement agencies and policy makers on the implementation and enforcement of the proposed Biosafety Act organized</p> <p>5.2 Database which is linked to the Biosafety Clearing House(BCH) and other national government agencies, R&D institutions and the national biotechnology network (NBBnet) constructed and maintained</p> <p>5.3 30-50 officers from different enforcement agencies on data management trained</p> <p>5.4 Workshop to share information from long-term monitoring results including cost-benefit analysis of releases of LMOs, for 60-80 scientists, sociologists, regulators, environmentalists, relevant govt. agencies, private industry and NGOs organized.</p>	<p>5.1.1 Workshop to inform collaborating government agencies on the need for their assistance in order to implement and administrate the proposed Biosafety Act.</p> <p>5.2.1 Training of Information Technology (IT) specialist to:</p> <ul style="list-style-type: none"> • Set up and maintain database • Link database to BCH <p>5.2.2 Training of government agencies on the use of BCH, including inputting data and accessing information</p> <p>5.3.1 Training of IT specialists to:</p> <ul style="list-style-type: none"> • Set up and maintain individual database • Link these databases to NBB database <p>5.4.1 Workshop on to share information on:</p> <ul style="list-style-type: none"> • cost-benefit analysis • ecological impact studies of environmental releases of LMOs
<p>6 Increased public awareness on</p>	<p>6.1 Website for NBB as a channel for</p>	<p>6.1.1 Training for IT specialist on biosafety issues and</p>

INTENDED OUTPUT	OUTPUT TARGETS	INDICATIVE ACTIVITIES
biotechnology and biosafety	<p>public communication and participation constructed.</p> <p>6.2 Training workshop on risk communication to 120 – 150 policy makers, enforcement officers, media personnel, NGOs and the public organized</p> <p>6.3 Consumer education and public awareness (CEPA) programmes for all stakeholders conducted.</p> <p>6.4 Stakeholders dialogue and feedback for 150 participants from industry, R&D institutes, universities, farmer groups, NGOs, etc. carried out</p>	<p>identifying information to be included in website without breach of confidential business information (CBI).</p> <p>6.2.1 Organize a workshop on explaining science to the public, to increase awareness on biosafety issues and Malaysia's international obligations</p> <p>6.3.1 Produce education kits, flyers, posters, documentary films for different target groups.</p> <p>6.4.1 Organize a series of dialogue sessions with industry, R&D institutes, universities, farmer groups, NGOs to promote better understanding on biosafety and biotechnology matters</p>

